

Remarks/Arguments:

A. Status of Application

Claims 1-29 were originally pending. In the Response to Restriction Requirement filed January 16, 2003, Applicants elected claims 1-18, 21-22, 25, and 26. In response to an additional restriction requirement, Applicants elected claims 1-4, 6-8, and 15-17. Claims 5, 9-14, and 18-29 have been withdrawn or cancelled as directed to a non-elected invention. Claims 1-4, 6-8, and 15-17 have been cancelled in favor of claims 30-39.

B. Application Papers

The Office Action Summary page of the Office Action mailed April 22, 2003 (hereafter "Office Action") indicates that the specification was objected to by the Examiner (item 9), however, there is no explanation of the objection in the Office Action, and it is not apparent why the specification is objected to. The Applicants request withdrawal of the objection, or an explanation of the objection to the specification.

C. Confirmation of Election

Applicants confirm the election of Group I, claims 1-4, 6-8, and 15-17 with respect to SEQ ID NO.1, with traverse. These claims have been cancelled in view of newly added claims 30-39, which are directed to the same invention as recited in the claims of Group I.

D. Claim Objections

Claims 1 and 4 were objected to. Claims 1 and 4 have been cancelled herein.

E. Claim Rejections Under 35 U.S.C. § 112 (2)

Claims 2, 3, and 17 were rejected under 35 U.S.C. § 112 second paragraph as being indefinite. Claims 2, 3, and 17 have been cancelled herein. The subject matter of claims 2 and 3 is incorporated into newly added claims 31 and 32. Claims 31 and 32 clearly indicate the source of the cloned sequences. The subject

matter of claim 17 has been incorporated into newly added claim 39. Claim 39 does not recite "important sequences" or "etc." Withdrawal of the rejection is respectfully requested.

F. Claim Rejections Under 35 U.S.C. § 101

Claims 1-4, 6-8, and 15-17 were rejected under 35 U.S.C. § 101 as lacking patentable utility. While claims 1-4, 6-8, and 15-17 have been cancelled, the subject matter of these claims is recited in the newly added claims 30-39. The Applicants traverse the rejection to the extent it applies to claims 30-39, and submit that the invention as recited does have patentable utility.

The Office Action states that the claimed invention is not "supported by either specific, substantial or a well-established utility." To make a prima facie showing of no specific and substantial credible utility, the Examiner must provide: (1) an explanation that clearly sets forth the reasoning used in concluding that there is no known well established utility for the claimed invention that is both specific and substantial; (2) support for factual findings relied upon in reaching this conclusion; and (3) an evaluation of all relevant evidence of record. This record must establish by a preponderance of the evidence that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the applicant for the claimed invention. Federal Register, Vol. 66, No.4 January 5, 2001. Here, evidence supporting a prima facie case has not been provided.

The Office Action states that the invention lacks a specific asserted utility because "the disclosed use of the nucleic acid is not specific and is generally applicable to any nucleic acid." Office Action, page 9. The specification clearly establishes that the present invention is useful in regulating dormancy of tea bushes. The nucleic acid of SEQ ID NO. 1 can be used to modulate winter dormancy in plants. Specification paragraphs [0052]-[0053], and Example 8.

The Office Action further asserts that "modulating winter dormancy using the novel genes in the plants after transferring these genes using the techniques such as biolistic mediated transformation" is a non-specific use applicable to nucleic acids in general and not particular to the nucleic acid being claimed. Office Action, page 9, first

paragraph. Certainly, the specific use of modulating winter dormancy in plants is not generally applicable to any nucleic acid. Chart 2 of the Background section of the specification lists several specific genes and proteins that have been implicated in the dormancy phenomenon in a variety of plant species. This list includes the phosphorylase enzyme in duckweed plant, and β - and α - amylase enzymes in aquatic and grain plants respectively. These are specific enzymes that have been uniquely associated with winter dormancy in select plant species. These examples illustrate that dormancy related genes and proteins vary among different plant species, but are specific in function, and the relation of their DNA to winter dormancy is not a generalized relationship applicable to "any nucleic acid." In contrast, the Office Action provides no evidence that nucleic acids in general can modulate winter dormancy in tea plants. Without evidence to the contrary, the Applicants have established that the claimed invention has a highly specific utility in modulating winter dormancy in tea plants.

The Office Action further asserts that the present invention lacks a substantial utility. The Applicants assert that the invention has a substantial utility in modulating dormancy in plants. Reduced dormancy periods, as well as extended dormancy periods can have severe agricultural and economic ramifications if untimely. See Specification, paragraphs 10-11. The specification also establishes that the "[m]odulation of dormancy has been and will continue to be a key issue in agriculture system[s]." Specification paragraph [0010]. Modulation of plant dormancy through the claimed gene sequences has the potential to save billions of tons of tea and food grains from rot as the introduction of these sequences could delay maturation, and thus prevent rot of unused product. Accordingly, the invention can have a tremendous impact on food supplies, especially in developing agricultural countries. By having such a tremendous impact on potential food supplies, the utility of the invention is certainly substantial.

While the Office Action did not assess the credibility of the invention's utility (Office Action, page 9, second paragraph), the Applicants submit that the utility of modulating winter dormancy in tea plants is credible. Example 8 of the specification establishes that the DNA sequence of SEQ ID NO:1 was down-regulated (i.e. showed reduced expression) in dormant apical buds as compared to non-dormant buds, and

forced non-dormant buds. The demonstrated correlation supports the Applicants' utility assertion, such that the asserted utility is credible.

In view of the foregoing and the teachings from the specification, the Applicants submit that claims 30-39 do have patentable utility, satisfying all the requirements of 35 U.S.C. § 101. Accordingly, withdrawal of the rejection is respectfully requested. Notwithstanding the Applicants' rebuttal, if the Examiner believes that the utility asserted by the Applicants is not specific, substantial and credible, or well established, Applicants invite the Examiner to submit an affidavit to his opinion with scientific basis for his factual conclusions. (see 37 C.F.R. § 1.104(d)(2); MPEP 2144.03)

G. Claim Rejections Under 35 U.S.C. § 112(1)

1. *Rejection based on lack of enablement*

The specification is objected to and claims 10-13 and 16-19 are rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention. Specifically, the Office Action stated that since the claimed invention is not supported by a specific, substantial, and credible asserted utility or a well established utility for the reasons set forth in the 35 U.S.C. § 101 rejection, one skilled in the art would not know how to use the claimed invention. Applicants traverse this rejection.

The rejection, though asserted under 35 U.S.C. § 112, first paragraph, is based on the allegation that the asserted function of the polynucleotides of the present invention lack patentable utility. Under the Utility Examination Guidelines, for rejections for want of utility under 35 U.S.C. § 101, a rebuttal to a rejection for lack of utility is equally applicable to a rejection based on lack of utility framed under 35 U.S.C. § 112. (See Revised Utility Examination Guidelines, Federal Register, Volume 64, Number 244, December 21, 1999, last paragraph) Accordingly, the Applicants' responses to the 35 U.S.C. § 101 rejection above are incorporated by reference here in response to the 35 U.S.C. § 112(1) rejection. Applicants respectfully contend that both rejections are not well founded in the facts of the present case and should be withdrawn.

2. *Rejection based on lack of written description*

While the Applicants appreciate the acknowledgement by the Office Action that SEQ ID NO:1 is novel and unobvious, and an explicitly disclosed species of the claim, the Applicants traverse the rejection under 35 U.S.C. § 112(1) based on a lack of written description. Specifically, the Office Action asserts that by including "comprising" language, the claims encompass species, such as splice variants, cDNAs, and genomic DNA that are not specifically set forth. According to the Written Description Examination Guidelines;

[a]n applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. **If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met.**

Federal Register, Vol. 66, No. 4, January 5, 2001 (emphasis added).

The Guidelines recite further, "[d]escribing the complete chemical structure, i.e., the DNA sequence, of a claimed DNA is one method of satisfying the written description requirement, but it is not the only method. See *Eli Lilly*, 119 F.3d at 1566, 43 USPQ2d at 1404 ("An adequate written description of a DNA * * * requires a precise definition, *such as* by physical properties." (emphasis added, internal quote omitted)). Therefore, there is no basis for a *per se* rule requiring disclosure of complete

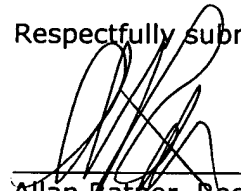
DNA sequences or limiting DNA claims to only the sequence disclosed." Written Description Guidelines, Federal Register, Vol. 66, No. 4, January 5, 2001.

Applicants submit that, based on the information provided in the specification of the present invention, one of ordinary skill in the art would undoubtedly be able to make or identify a polynucleotide that is "[a] DNA sequence comprising the polynucleotide sequence of SEQ ID NO:1, wherein the polynucleotide sequence is expressed or repressed during winter dormancy in apical buds of a first *Camellia sinensis* L. (O.) Kuntze (tea) bush or tree." Newly added claim 30. The claim recites an exact DNA sequence, a particular species of plant, and couples that written description with functional language incorporating a correlation between the sequence expression and dormancy modulation. The functional and localization description of the sequence in combination with the explicit recitation of the sequence is adequate written description to support "comprising" language according to the Written Description Guidelines and Training Materials. Accordingly, Applicants respectfully request withdrawal of the rejection.

H. Summary

In view of the foregoing amendments and remarks, the Applicants submit that this application is in condition for allowance and respectfully request early and favorable notification to that effect. If it would expedite prosecution of this application, the Examiner is invited to confer with Applicants' undersigned representatives.

Respectfully submitted,



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Reply to Office Action of April 22, 2003

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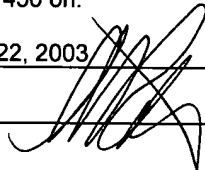
Dated: August 22, 2003

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